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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,687	10/05/2000	Stephen M. Allen	BB1162 US NA	1467
27123	7590	08/29/2006	EXAMINER HOWARD, ZACHARY C	
MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			ART UNIT 1646	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/679,687

Applicant(s)

ALLEN ET AL.

Examiner

Zachary C. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,27-30,32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,27-30,32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 6/12/06 has been entered.

Status of Application, Amendments and/or Claims

The amendment of 6/12/06 has been entered in full. Claim 25 is amended. Claim 26 is canceled. Claims 31 and 33 were cancelled previously.

Claims 25, 27-30, 32 and 34 are under consideration in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

All rejections of claim 26 are moot in view of Applicants' cancellation of the claim.

Maintained Rejections

Claim Rejections - 35 USC § 101, utility

Claims 25, 27-30, 32 and 34 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial utility or a well-established utility.

In view of Applicants' persuasive arguments at pg 6-7 of the 6/12/06 Office Action (citing Aoki, 2003 and Lemoine, 1999) and the 91.5% identity between the polypeptide of SEQ ID NO: 2 and ZmSUT1 as taught by Aoki, the Examiner concedes that based on sequence homology alone instant SEQ ID NO: 1 more likely than not encodes a polypeptide of SEQ ID NO: 2 with sucrose transport activity. However, the

Examiner maintains that the identification of a nucleic acid found in maize that encodes a polypeptide with "sucrose transport activity" does not provide a specific and substantial utility for the novel claimed polynucleotides. The teachings of Lemoine (published in 2000 after the filing date of the instant application) support this position. Despite the similarities between the twelve known plant sucrose transporters, Lemoine teaches that individual plant species have multiple sucrose transporters and little is known about their specific functions. Lemoine teaches "[t]he existence of several sequences related to already known sucrose carriers in the Arabidopsis database indicate that a whole family of sucrose transporter genes is present in one single plant... The next challenge will be to unravel the exact function of the new genes and their role in the plant." Similarly, Aoki et al (2003, *Plant Cell Physiol*, 44(3): 223-232) reports that five different SUT sucrose transporters have been found in rice (pg 224) with different expression patterns for 4 out of 5 (pg 227). Aoki further reports that other researchers have found two SUT sucrose transporters in barley, each with a different expression pattern (pg 223). Aoki concludes "The differential expression patterns of the five *OsSUT* genes in rice plants observed in this work suggest that the SUT gene family has many roles in both source and sink tissues, and at different developmental stages. It would be helpful to produce and analyse suppression/knock-out lines, in order to fully understand the physiological roles of the SUT gene family in rice plants. It is also noteworthy that in each tissue tested, at least four *OsSUT* genes are apparently expressed. This overlapping expression may imply diverse roles of the five *OsSUT* proteins in membrane-mediated sucrose transport processes or could represent expression in different cell types" (pg 230). The Examiner agrees that instant SEQ ID NO: 2 is 91.5% similar to a maize sucrose transporter taught by Aoki (1999). However, even if the encoded protein can transport sucrose, this only indicates that maize has two different sucrose transporters, which may or may not have similar biological functions. While Aoki (1999) teaches the expression pattern of the maize sucrose transporter identified therein, the expression pattern of instant SEQ ID NO: 2 has not been demonstrated. The expression pattern may or may not be the same for the two maize sucrose transporters.

Applicants' arguments (6/12/06) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

Applicants submit at pg 3 that the Examiner has not established a *prima facie* showing that a person of ordinary skill in the art would more likely than not consider that the asserted utility is not specific and substantial. Applicants discuss the standard for utility on page 4, citing "Chisum on Patents" (2006). Applicants further submit at pg 4-6 that the specification teaches that sucrose transporters have utility in controlling grain fill. Applicants submit that Scofield et al (2002) teaches that antisense suppression of the rice sucrose transporter gene *OsSUT1* leads to impaired grain filling. Applicants point out that *OsSUT1* (SEQ ID NO: 26) is 81.7% identical to instant SEQ ID NO: 2. Applicants further submit that Hirose et al (1999) earlier saw high expression of levels of rice *OsSUT1* in panicles after heading and postulated it was involved in transport of sucrose into the filling grain. In conclusion, Applicants submit that an asserted utility for polypeptides having sucrose transport activity, such as use in grain filling and improving yield and quality is a specific, substantial and credible utility.

Applicants' arguments have been fully considered but are not found persuasive. The Examiner agrees with Applicants' characterization of the teachings of Scofield and Hirose. The Examiner agrees that Scofield (2002) shows that antisense suppression of the rice sucrose transporter gene, *OsSUT1*, leads to impaired grain filling. However, the teachings of Scofield and Hirose do not provide a specific and substantial utility for instant SEQ ID NO: 1 or 2. Rather, the teachings of Scofield demonstrate what is necessary in the art in order to conclude that a particular sucrose transporter can be used to control grain filling. Applicants have not shown that antisense suppression of instant SEQ ID NO: 1 leads to impaired grain filling in maize. Furthermore, the similarity between *OsSUT1* and instant SEQ ID NO: 2 does not allow one of skill in the art to know that the polynucleotide encoding SEQ ID NO: 2 could be used to control grain filling. As described above, the physiological function of specific plant sucrose transporters is not well understood and multiple sucrose transporters are found in a single species of plant. Applicants have not shown where instant the polynucleotide encoding SEQ ID NO: 2 is expressed in the maize plant. It may be expressed in

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different tissues than *OsSUT1*. Even if the expression pattern in tissues of the polynucleotide encoding SEQ ID NO: 2 is similar to *OsSUT1*, it does not necessarily follow that antisense suppression of said polynucleotide would lead to impaired grain filling. As taught by Aoki (2003) and described above, the art appreciates that sucrose transporter genes could be expressed in different cell types within the same tissue and therefore have different functions. In a review of the state of the art regarding plant sucrose transporters, Truernit et al (2001) teaches, "But as more genes encoding plant sucrose transporters are identified, it is becoming evident that they are likely to have a variety of very distinct functions in plants" (Truernit, 2001. *Current Biology*. 11:R169-R171). For these reasons, it is maintained that the claimed invention, polynucleotides encoding instant SEQ ID NO: 2, is not supported by either a specific and substantial utility or a well-established utility. A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Applicants argue at pg 7 that it is not necessary to show where instant SEQ ID NO: 2 is expressed in the maize plant. Applicants argue that the specification teaches (pg 12) that the isolated polynucleotide can be used with a variety of plant promoter sequences in non-endogenous settings.

This argument has been fully considered but is not found persuasive. While it is true that the specification teaches that polynucleotides of the instant invention, for example SEQ ID NO: 1, can be expressed in a non-endogenous location in a plant, the specification does not provide a specific and substantial utility for such non-endogenous expression. The specification only indicates that the polynucleotides can be expressed in a non-endogenous location, without indicating a utility for such expression, other than suppression of grain filling (by antisense technology), which as stated above is not a specific and substantial utility.

Applicants argue at pg 8, that "even if a showing of expression pattern was necessary, the Office Action concedes that the expression pattern of the maize sucrose transporter *ZmSut1* is demonstrated in Aoki (1999)...and *ZmSUT1* is within the scope of the claims".

This argument has been fully considered but is not found persuasive. The claims as amended are limited to polypeptides that are 95% identical to SEQ ID NO: 2. The ZmSUT1 gene is 91.5% identical to instant SEQ ID NO: 2, and therefore the ZmSUT1 gene does not fall within the scope of the claims. Furthermore, the expression pattern of ZmSUT1 is only specific to the exact sequence, and it is not predictable whether other closely related sequences have the same expression pattern, as evidenced by the teachings of Aoki (2003) cited above regarding rice and barely sugar transporters.

Applicants further argue (pg 9) that the “use of nucleic acid fragments of the instant invention to isolate cDNAs and genes encoding from the same or other plant species (as described in the specification at page 10, lines 7-13) would yield targets with real and substantial uses. Applicants argue that “it is a credible and specific utility of SEQ ID NO: 2 to use SEQ ID NO: 2 in assays for OsSUT1, which has the real-world substantial utility of modulating grain filling in rice”.

This argument has been fully considered but is not found persuasive. Applicants refer to “use of nucleic acid fragments” and then “use of SEQ ID NO: 2” (which is a polypeptide) in the same paragraph. Therefore, it is unclear whether Applicants are arguing that the nucleic acid or polypeptide could be used in assays for OsSUT1. However, the Examiner believes that the Applicants are arguing that the claimed polynucleotides could be used to isolate cDNAs and genes encoding OsSUT1. Applicants similarly argue that SEQ ID NO: 2 can be used in assays for ZmSut1 (maize sucrose transporter taught by Aoki, 1999).

This argument has been fully considered but is not found persuasive. The instant specification does not teach that the instant polynucleotide can be used to isolate OsSUT1 or that OsSUT1 has a role in grain filling. While the sequence of OsSUT1 was known in 1997 (as reported by Scofield on page 816), the role of OsSUT1 in grain filling was not established until 2002 by Scofield. This asserted utility is not specific because the instant Application does not report that OsSUT1 is a sequence that can identified by using SEQ ID NO: 1 and is not substantial because the role of OsSUT1 in grain filling was not established at the time of filing of the instant application. With regard to ZmSUT1, the sequence of this protein was not available at the effective filing date of the

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instant application (as Applicants argue at page 7 of the 6/12/06 response).

Furthermore, this ZmSUT1 sequence does not appear to have an asserted substantial utility at the time of filing of the instant application. Furthermore, any polynucleotide sequence with homology to OsSUT1 or ZmSUT1 could be used to identify those sequences. Therefore, the asserted utility is not specific to the claimed polynucleotides.

Claim Rejections - 35 USC § 112, enablement

Claims 25, 27-30, 32 and 34 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention

Applicants' arguments (6/12/06) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

In the response dated 6/12/06 Applicants note that the enablement rejection was made with respect to 'how to use' the invention in connection with the lack of utility rejection and therefore refer to their remarks with regard to utility.

Applicants' arguments have been fully considered but are not found persuasive. The rejection for lack of a specific and substantial asserted utility or a well-established utility has been maintained for the reasons set forth above. Therefore, it is maintained that one of skill would not know how to use the claimed invention.

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Conclusion

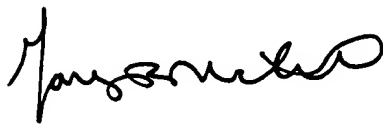
No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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